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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim-Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD., and HANMI HOLDINGS CO., LTD. Defendants and Counterclaim-Plaintiffs.	Civil Action No. 3:11-CV-00760 (JAP)(TJB) Hon. Joel A. Pisano, USDJ Hon. Tonianne J. Bongiovanni, USMJ **Motion Date: January 22, 2013**

BRIEF IN SUPPORT OF ASTRAZENECA'S MOTION FOR RECONSIDERATION OF CLAIM CONSTRUCTION

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INTRODUCTION

Pursuant to Local Rule 7.1(i), AstraZeneca moves for reconsideration of the Court's construction of the term "alkaline salt" in the December 12, 2012 opinion on claim construction. (D.I. 257) ("Opinion"). The Court construed the term "alkaline salt" in independent claim 1 of U.S. Patent No. 5,714,504 ("the '504 patent") to be limited to the six specific salt species recited in dependent claim 3. Plaintiffs submit, with respect, that the Court overlooked or misapprehended the effect of the prosecution history on the construction of "alkaline salt."

In arriving at its construction, the Court appears to have overlooked the Federal Circuit's controlling decision in *Rambus Inc. v. Infineon Technologies,* 318 F.3d 1081, 1094-95 (Fed. Cir. 2003), which holds that a court should not construe a patent claim term more narrowly than its plain and ordinary meaning unless the intrinsic evidence as a whole, including the prosecution history, consistently and uniformly requires the narrower construction. In its analysis, the Court does not mention the '504 patent prosecution history. Assessing such relevant intrinsic evidence is necessary to proper claim construction.

Also, in arriving at its current construction, the Court rejected the presumption that underlies the principle of claim differentiation. The intrinsic evidence is not consistent with the Court's rejection of the presumption. In finding an exception to the presumption of "claim differentiation," the Court appears to

have relied exclusively on the patent specification without considering the patent prosecution history. The court reasoned that the patent specification defined "alkaline salt" to six specific salt species and was sufficient to overcome the presumption of claim differentiation, relying in part upon *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361 (Fed. Cir. 2005), and *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533 (Fed Cir. 2000). (Opinion at 6-7). Yet, the prosecution history of the '504 patent demonstrates that claims 1 and 3 differ in scope.

Plaintiffs also respectfully submit that the Court may have misapprehended the applicability here of *Seachange* and *Laitram*. *Seachange* is inapplicable because it concerned the differentiation in scope between claims unrelated by dependency. *Seachange* does not concern facts, as here, where the differentiation in scope is between independent and dependent claims. When assessing independent and dependent claims, the presumption of different scope is at its strongest. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 905-6 (Fed. Cir. 2000). And, in *Laitram*, the Federal Circuit was careful to explain that under its construction of the disputed claim language, the compared claims did not "have exactly the same scope and, thus, claim differentiation [wa]s maintained." 939 F.2d at 1538.

Also, because the Court has construed the term "pharmaceutically acceptable salt" in U.S. Patent 5,877,192 ("the '192 patent") to have the same

meaning as "alkaline salt," Plaintiffs also respectfully request the Court reconsider its construction of "alkaline salt" in the context of the '192 patent.

LEGAL STANDARD

Local Rule 7.1(i) provides that a party moving for reconsideration must set forth "the matter or controlling decisions which the party believes" the Court overlooked in its prior decision. Local Rule 7.1(i). To prevail, the movant must show that "dispositive factual matters or controlling decisions of law were brought to the Court's attention but not considered."[1] *Stolinski v. Pennypacker*, Civ. No. 07-3174, 2009 WL 1651168, at *2 (D.N.J. June 11, 2009) (citation omitted). The court will entertain a motion for reconsideration where the court has overlooked matters that, if considered, might reasonably have resulted in a different conclusion. *U. S. v. Compaction Sys. Corp.*, 88 F. Supp. 2d 339, 345 (D.N.J. 1999). That standard is met here.

ARGUMENT

I. The Court Appears Not to Have Applied the Federal Circuit's Controlling Decision in *Rambus* in Construing "Alkaline Salt."

There is a "heavy presumption" that claim terms carry the plain and ordinary meaning. (D.I. 176 at 7). In construing "alkaline salt," the Court concluded that language in the specification required a narrower definition of that

[1] The evidence cited in this paper was brought to the attention of the Court during the claim construction proceedings.

term—one that included only six salts. (Opinion at 6). In doing so, however, the Court did not appear to apply the Federal Circuit's controlling decision in *Rambus*. *Rambus* makes clear that, before limiting the full scope of the claim on the basis of statements in the specification, all intrinsic evidence, including the specification as a whole and the prosecution history, must uniformly support that limitation. *See id.* Although AstraZeneca cited *Rambus* in briefing and argued that it precluded limiting "alkaline salt" in the manner that Hanmi proposed, (D.I. 176 at 5), the Court did not cite *Rambus* or appear to follow that decision in construing the term in question. (*See generally* Opinion at 5-8).

In *Rambus*, the Federal Circuit explained that while a couple of statements in the specification "taken alone" may suggest some limitation of the term "bus," "the remainder of the specification and prosecution history show[ed] that *Rambus* did not clearly disclaim or disavow such claim scope." 318 F.3d at 1094-95. The Federal Circuit observed that while statements about the "present invention" may sometimes limit the meaning of claim terms in patent cases, "such language must be read in context of the entire specification and the prosecution history." *Id*. at 1094. And when one reviewed the entire specification and prosecution history in *Rambus*, it was clear that, notwithstanding a couple of potentially limiting statements in the specification, the inventors did not intend to limit the scope of "bus." *Id*. at 1095.

This Court's decision is inconsistent with *Rambus'* in that the Court appears not to have considered (or given necessary weight to) the patent prosecution history. *Rambus* provides a clear directive that potentially limiting statements in the specification must be viewed in the context of the prosecution history as well. 318 F.3d at 1094. Here, the prosecution history supports the full claim scope of "alkaline salt." (D.I. 176, at 7-8).

When the application for the '504 patent was filed, the broadest compound claim was limited to six species of salts:

> 1. An optically pure enantiomeric compound comprising a **Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$ salt** of [(+)-omeprazole] or [(-)-omeprazole], wherein R is an alkyl with 1-4 carbon atoms.

(Doc. 111.0 at 37, emphasis added; for convenience, copy attached as Exh. A; Exhibits referenced herein are attached to the accompanying declaration of Joshua I. Rothman).

Following a January 1997 interview in which the Examiner noted that the scope of the claims "will depend on the data submitted," (D.I. 111.0 at 76-77, Exh. B), AstraZeneca cancelled all of the original claims 1-34, and added new claims 35-44, which later issued as claims 1-10 of the '504 patent. (D.I. 111.2 at 5, Exh. C).

Claim 35 replaced cancelled original claim 1, and used the *broader* term "alkaline salt," thereby expanding coverage beyond the mere six salts that had

previously been listed in original claim 1. Applicants presented data demonstrating that esomeprazole in the form of both sodium ("Na^{+}") and magnesium ("Mg^{2+}") salts supported the patentability of the broadest claim. (D.I. 111.2 at 20-34, Exh. D). Applicants also argued repeatedly that this data showed that *any* alkaline salt of esomeprazole provided surprising and unexpected results that support patentability. For example, applicants argued as follows:

> As shown in the Andersson Declaration the (-)-omeprazole enantiomer, as administered in the form of its *alkaline salts*, unexpectedly exhibits a different and more advantageous pharmacokinetic profile than the racemic mixture or the (+)-enantiomer of omeprazole.

(*Id.* at 8, emphasis added, highlighted in Exh. E); and:

> As discussed at the interview, the pharmaceutical formulations for oral administration comprising pure solid state *alkaline salts* of the (-)-enantiomer of omeprazole to which the new claims are directed, are patentable over the prior art and the cited references.

(*Id.* at 12, emphasis added, highlighted in Exh. E). *See also* eight other highlighted portions of Exh. E and two highlighted portions of Exh. D.

The Examiner allowed *both* the new broad independent claim reciting "alkaline salt" and the new narrower dependent claim reciting the six salt species. Plainly, applicants and the Examiner both viewed these two claims as having different scope. If the Examiner had concluded that the specification defined

"alkaline salt" as being limited to just the six species, she never would have allowed both claim 1 and claim 3.

The Court's reliance on portions of the specification to find intent to limit "alkaline salt" in claim 1 to only the six species cannot be reconciled with the prosecution history. Under *Rambus*, such reconciliation is required. Here, as in *Rambus*, when isolated statements in the specification are viewed in the context of the prosecution history, support for the conclusion that applicants clearly intended to confer a narrow scope on the claims disappears.

II. The Court Appears to Have Placed Undue Reliance on the Language of the Specification and Relied Upon Inapposite Precedent in Addressing the Presumption of Claim Differentiation.

This Court's construction of "alkaline salt" should be reconsidered because the present construction is contrary to the presumption of claim differentiation, and would thereby render claim 3 meaningless. Claim 3 is directed to the "pharmaceutical formulation according to claim 1," with the added limitation that the "alkaline salt" is restricted to the salts Na^+, Mg^{2+}, Li^+, K^+, Ca^{2+} or $N^+(R)_4$. (Opinion at 7). Under the Court's construction, however, "alkaline salt" in claim 1 is already limited to these six particular salts, meaning that the added limitation in claim 3 would not differentiate that claim from claim 1, rendering claim 3 meaningless.

In its opinion, this Court reasoned that the claim differentiation doctrine was "not a hard and fast rule," and that the "relevant intrinsic evidence" required the Court's interpretation. (Opinion at 7). However, Federal Circuit precedent emphasizes that the presumption of claim differentiation is "especially strong" when, as here, "the limitation in dispute is the only meaningful difference between an independent and dependent claim." *Liebel-Flarsheim*, 358 F.3d at 910. Under these circumstances, the presumption can only be overcome by "strong contrary evidence." *Interdigital Communications v. ITC*, 690 F.3d 1318, 1324 (Fed. Cir. 2012). It is respectfully submitted that the cases relied upon by the Court are inapposite to the matter at hand. In addition, as noted above, in discussing the relevant intrinsic evidence the Court did not address the patent prosecution history.

First, in concluding that the presumption of claim differentiation had been overcome, this Court cited *Seachange* and *Laitram*. (Opinion at 7). But *Seachange* is inapplicable here; it concerned the differentiation in scope between separate claims not related by dependency. *Seachange* did not concern the situation where, as here, the differentiation in scope is between independent and dependent claims. It is just this situation where the presumption of different scope is at its strongest. *Liebel-Flarsheim*, 358 F.3d at 905-06. This Court also relied upon *Laitram*. There, however, the Federal Circuit was careful to explain that

under its construction of the disputed claim language, the compared claims did not "have exactly the same scope and, thus, claim differentiation [wa]s maintained." *Id.* at 1538.

Second, while this Court reasoned that the presumption of claim differentiation had been overcome by intrinsic evidence, the intrinsic evidence as a whole did not support this view. The Court relied only on language in the specification and does not appear to consider all intrinsic evidence (*e.g.*, the prosecution history). The prosecution history makes clear that both the applicants and the Examiner understood "alkaline salt" to be broader than simply the six salts to which the Court has limited that term. If the applicants had intended to limit "alkaline salt" in claim 1 to the six salts listed in claim 3, why not explicitly recite six species in claim 1 and omit claim 3 altogether? And, if the Examiner had believed that the specification defined "alkaline salt" as being limited to just the six species, she never would have allowed both claim 1 and claim 3. In this case, the evidence is insufficient to overcome the strong presumption of claim differentiation, let alone the necessary "strong contrary evidence." *Interdigital*, 690 F.3d at 1324.

CONCLUSION

For the foregoing reasons, AstraZeneca respectfully requests that the Court reconsider its December 12, 2012 order on claim construction, and construe

the ’504 patent claim term “alkaline salt” consistent with its plain and ordinary meaning, as AstraZeneca proposed in its claim construction submissions. Because the Court has ruled that the claim term “pharmaceutically acceptable salt” in the ’192 Patent carries the same meaning as “alkaline salt,” the Court should likewise reconsider that construction, as proposed in AstraZeneca’s claim construction submissions.

Respectfully submitted,

Dated: December 21, 2012

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